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EXAMINER

STAPLES, MARK

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,052	<b>Applicant(s)</b> DIRKS ET AL.	
	<b>Examiner</b> Mark Staples	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/26/2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26, 29, 30, 32, 35-43 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26, 29, 30, 32, 35-43, and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Change of Examiner**

1. The examiner of record has changed. Please direct future correspondence to Examiner Staples whose telephone number is (571) 272-9053.

### **Claims Pending**

2. Applicant's amendment of claims 26, 29, 35, 39, 41, 42, 43, and 48; and the cancellation of claims 1-25, 27, 28, 31, 33, 34, 44-47, and 52-54 in the paper filed on 11/26/2007 are acknowledged.

Claims 26, 29, 30, 32, 35-43, and 48-51 are pending and at issue.

Applicant's arguments filed on 11/26/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Rejections that are Moot / Withdrawn**

#### ***Rejections of Cancelled Claims Moot / Withdrawn***

3. The rejections of cancelled claims 27, 28, 31, 33, and 34 are moot and therefore are withdrawn.

***Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph***

4. The rejection of claims 39-40 under 35 USC § 112 Second Paragraph is withdrawn in light of Applicant's amendment to provide antecedent basis for the limitation "the consensus sequence" in claim 26.
5. The rejection of claim 48 under 35 USC § 112 Second Paragraph is withdrawn in light of Applicant's amendments to this claim to recite "The method" and to provide further limitation to the method of antecedent claim 43.

***Claim Rejections Withdrawn - 35 USC § 102***

6. The rejections of claims 26, 30, 32, and 36-40 under 35 U.S.C. 102(b) as being anticipated by Caskey et al. (US 5,582,989) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.
7. The rejections of claims 26, 30, 32, 37, and 39-40 under 35 U.S.C. 102(e) as being anticipated by Nicholson, Geoffrey Charles (US 7,105,480 B1) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.
8. The rejections of claims 26, 30, 32, and 36-40 under 35 U.S.C. 102(b) as being anticipated by Thomann et al. (WO 01/53529 A2) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

9. The rejections of claims 26, 30, 32, 39-43, and 48 under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (US 5,973,133) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections Withdrawn - 35 USC § 103(a)***

10. The rejections of claims 29, 35, 41-43, and 48-51 under 35 U.S.C. 103(a) as being unpatentable over Caskey et al. (US 5,582,989) and further in view of Vos et al., "AFLP, A new technique for DNA fingerprinting," Nuc.Acids.Res., 1995, Vol.23, No.21, pp.4407-4414, as cited on the IDS dated 1/3/06 are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

11. The rejections of claims 29, 35, 41-43, and 48 under 35 U.S.C. 103(a) as being unpatentable over Nicholson, Geoffrey Charles (US 7,105,480 B1) and further in view of Vos et al., "AFLP, A new technique for DNA fingerprinting," Nuc.Acids.Res., 1995, Vol.23, No.21, pp.4407-4414, as cited on the IDS dated 1/3/06 are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

12. The rejections of claims 49-51 under 35 U.S.C. 103(a) as being unpatentable over Nicholson, Geoffrey Charles (US 7,105,480 B1), in view of Vos et al. (1995) and further in view of Thomann et al. (WO 01/53529 A2) are moot. Applicant's arguments

with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

13. The rejections of claims 36 and 38 under 35 U.S.C. 103(a) as being unpatentable over Nicholson, Geoffrey Charles (US 7,105,480 B1) and further in view of Thomann et al. (WO 01/53529 A2) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

14. The rejections of claims 29, 35, 41-43, and 48-51 under 35 U.S.C. 103(a) as being unpatentable over Thomann et al. (WO 01/53529 A2) and further in view of Vos et al., "AFLP, A new technique for DNA fingerprinting," Nuc.Acids.Res., 1995, Vol.23, No.21, pp.4407-4414, as cited on the IDS dated 1/3/06 are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

15. The rejections of claim 35 under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (US 5,973,133) and further in view of Vos et al., "AFLP, A new technique for DNA fingerprinting," Nuc.Acids.Res., 1995, Vol.23, No.21, pp.4407-4414, as cited on the IDS dated 1/3/06 are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

16. The rejections of claims 36 and 38 under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (US 5,973,133) and further in view of Thomann et al. (WO 01/53529 A2) are moot. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

**New Rejections Necessitated by Amendment**

***New Claim Rejections - 35 USC § 103***

17. Claims 26, 29, 30, 32, 35-43, and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (1996, Molecular Breeding 2: 225-238, The comparison of RFLP, RAPD, AFLP and SSR (microsatellite) markers for germplasm analysis) and Thomann et al. (WO 01/53529 A2, published 26 July 2001, RAPID DETERMINATION OF GENE STRUCTURE USING cDNA SEQUENCE, previously cited).

Although Applicant's arguments are moot in view of new grounds of rejection, it is noted that Applicant argues Thomann et al. (WO 01/53529 A2) teach "tiled" primers. However this not the only type of primers which Thomann et al. teach, and regardless the instant claims do not exclude the use of "tiled" primers.

Regarding claims 26, 29, and 41-43 Powell et al. (1996) teach methods for analyzing or amplifying a nucleic acid sequence, specifically markers of polymorphism for germplasm analysis (entire article, especially the Title), comprising analyzing or amplifying at a nucleic acid sequence with at least one AFLP primer, that is primers which are used to amplify and detect amplified fragment length polymorphisms (AFLP, see 1<sup>st</sup> paragraph on p. 225 continued to p. 226) which contains at least one selective nucleotide at its 3' end by teaching: "all [AFLP] primers carried either two or three nondegenerate, selective nucleotides at the 3' end" (see 1<sup>st</sup> full sentence on p. 228),

wherein the nucleic acid sequence comprises a restriction fragment with one oligonucleotide adapter at both ends by teaching: “AFLP conditions were essentially as described by Zabeau [57], with minor modifications [28]. Briefly, total genomic DNA from each soybean cultivar was digested with . . . restriction enzyme combinations, then double-stranded adaptors were ligated to the fragment ends” (which produces a mixture of adapter-ligated restriction fragments, see 1st sentence of last paragraph on p. 227), and wherein said restriction fragment is derived from genomic DNA which is total genomic DNA.

Further regarding claims 26 and 41-43, Powell et al. (1996) teach analyzing and detecting conserved/consensus polymorphisms (to discriminate between subspecies of an organism, see 2nd paragraph on p. 231).

Regarding claim 35, Powell et al. (1996) teach that the primer/probes can have random sequences (see footnote 3 to Table 2 and see random primer methods in the 1<sup>st</sup> paragraph on p. 234).

Regarding claims 26 and 41-43, Powell et al. (1996) do not teach specifically analyzing or amplifying a nucleic acid with an S3P primer, comprising at least part of a consensus sequence of a splice-site border sequence.

Regarding claims 26, 30, 32, 41-43, and 48 Thomann et al. (WO 01/53529 A2) teach specifically teach analyzing or amplifying a nucleic acid with an S3P primer, comprising at least part of a consensus sequence of a splice-site border sequence.



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Thomann et al. a method for analyzing or amplifying a nucleic acid sequence, comprising analyzing or amplifying a nucleic acid with an S3P primer [claim 26], wherein the nucleic acid sequence contains or is suspected to contain, an intron-exon junction and/or a splice site [claim 30] and the S3P primer is in an intron-to-exon orientation or in an exon-to-intron orientation [claim 32] (see pg.3, lines 24-29; pg.4, lines 5-15; pg.13, lines 13-25; pg.14, lines 23-25; pg. 15, lines 15-18; pg.16, Table IV, primers 6 and 8; pg.17, line 16; pg.26-27 Table VII, primers 947L (13) and 950U (14) and description of Table VIII).

Regarding claims 36, 39-40, and 49-51, Thomann et al. (WO 01/53529 A2) teach the method wherein the S3P primer comprises a conserved splice site border sequence or at least part of a consensus sequence, and is specific for a splice site selected from the group consisting of GU-AG introns, AU-AC introns, Group I introns, Group II introns, Group III introns, Twintrons, Pre-tRNA introns, and splice sites that are identified using computer based splice site identification methods (see pg.4, lines 5-15, pg.13, lines 13-25 and pg.10, lines 8-9).

Regarding claims 37-38, Thomann et al. (WO 01/53529 A2) teach the method wherein the S3P primer contains a total of between 8 and 20 nucleotides or wherein between 4 and 10 nucleotides present in the S3Pprimer primer are complementary to the conserved region or consensus sequence of the splice site (see pg.10, lines 1-2; Table IV, primers 6 and 8; pg.17, line 16; pg.26-27 Table VII, primers 947L (13) and 950U (14) and description of Table VIII).

Further regarding claims 26 and 41-43, Thomann et al. (WO 01/53529 A2) teach that their methods are useful for analysis and detection of polymorphisms (see pages 6 and 7) and that their methods can be used with additional primers other than S3P primers (see for example claims 13 and 14).

Regarding claims 26 and 41-43, Thomann et al. (WO 01/53529 A2) do not specifically at least one AFLP primer for analysis and detection of amplified fragment length polymorphisms, AFLP.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods using primer to analyze

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and detect polymorphisms including AFLP of Powell et al. by also using an S3P primer as suggested by Thomann et al. with a reasonable expectation of success. The motivation to do so is provided by Thomann et al. who teach additional primers, including primers to analyze and detect polymorphisms, can be combined with S3P primers. Further motivation to do so is provided by Thomann et al. who teach: "A combination of all newly derived 5' and 3' sequence and intron sequence with the already published cDNA sequence is shown below (Figure 6) . . . Thus, all intron-exon boundaries and consensus splice sequences, relevant gene structure information, is provided by the method of the present invention without having to sequence the entire gene" (see p. 29, 2<sup>nd</sup> paragraph). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Reference of Interest**

18. Zabeau et al. (United States Patent No. 6,045,994 issued April 4, 2000) is made a reference of interest. Zabeau et al. teach selective restriction fragment amplification (see Title) and specifically teach ligating oligonucleotide adaptors to one or both ends of restriction fragments (see claim 1 step b). Zabeau et al. also teach that the restriction fragment can be double stranded (see column 3 lines 13-16 and see first example in Figure 2).

### **Conclusion**

19. No claim is free of the prior art.

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20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

March 26, 2008

/Young J Kim/

Primary Examiner, Art Unit 1637